REMARKS/ARGUMENTS

As discussed below, Applicants respectfully request withdrawal of the restriction requirement as it is overly restrictive and improper under the PCT's Unity of Invention standard. The present application is a U.S. national stage application of a PCT application which was filed on February 3, 2004. Therefore, the Unity of Invention standard applies.

I) Election with Traverse

As a preliminary matter however, as required and to reserve the right to appeal the restriction requirement if made final, Applicants make the following elections with traverse:

Applicants elect Group I, claims 1-26.

Regarding the species restrictions:

Applicants elect restenosis as the disease.

Applicants elect coating on stent as the local delivery system.

Applicants elect implantable stent as the interventional medical device.

Applicants elect CC-1065 as the bioactive agent.

II) Identification of Claims Readable on Elected Species

Below is a listing of claims readable on the elected species:

Restenosis as the disease: Claims 1-26.

Coating on stent as the local delivery system: Claims 1-26.

Implantable stent as the interventional medical device: Claims 24-26.

CC-1065 as the bioactive agent: Claims 1, 2, and 24-26.

III) Argument

Applicants respectfully traverse the present restriction requirement for the reasons below.

When making a lack of unity of invention requirement, the examiner must (1) list the different groups of claims and (2) explain why each group lacks unity with each other group (i.e., why there is no single general inventive concept) specifically describing the unique special technical feature in each group. MPEP § 1893(d).

Applicants submit that the Examiner has not met these requirements. The Examiner set forth two groups to elect from: Group I (claims 1-26) and Group II (claims 27-30). However, the Examiner has not specifically described the unique special technical feature in each group. The Examiner stated that the technical feature of Groups I and II is a system for treating or preventing atherosceloris, stenois, restenosis, smooth muscle cell proliferation, or other abnormal luminal cellular proliferation. (Restriction requirement dated 03/03/08, Page 2). Although a technical feature common among the groups was set forth, the Examiner did not specifically describing the unique special technical feature in each group as required by MPEP § 1893(d).

Also, the Examiner required Applicants to make four very narrow species elections: a single and specific disease, a single and specific local delivery system, a single and specific interventional medical device, and a single and specific bioactive agent with all its substituents fully accounted for. In imposing such a narrow species election requirement, the Examiner was required also to describe the unique special technical feature in each species group not simply Group I and II and show why they are different. Thus, the burden of setting forth a proper restriction requirement under the PCT's unity of invention standard was not met.

Also, the Examiner applied U.S. restriction practice in this case which is improper. The Examiner asserted that the species are drawn to materially different compositions, delivery agents, interventional medical devices and to functionally different illnesses and that search for each of the above species is not co-extensive particularly with regard to the literature search. The Examiner further asserted that a reference which would anticipate one species would not necessarily anticipate or even

make obvious another species. "Examiners are reminded that unity of invention (not restriction practice pursuant to 37 CFR 1.141-1.146) is applicable in international applications (both Chapter I and II) and in national stage applications submitted under 35 USC 371." MPEP 1893.03(d). Asserting that the restricted groups and species would be burdensome to search and that a reference which would anticipate one species would not necessarily anticipate or even make obvious another species, uses the prohibited standard according to restriction practice pursuant to 37 CFR 1.141-1.1146 in a national stage application. Simply stating that the species listed do not relate to a single general inventive concept under PCT Rule 13.1 (page 4, paragraph 1 of the restriction requirement dated 03/03/08) while applying the standard according to restriction practice pursuant to 37 CFR 1.141-1.1146 in support of the assertion, Applicants submit, cannot be a proper application of the unity of invention standard.

Indeed, when the Unity of Invention standard is appropriately applied, the Office should conclude that a single general inventive concept exists. Annex B of the Administrative Instructions Under the PCT (AI58 in MPEP) illustrates that the present case is one of the particular situations for which the method for determining unity of invention contained in Rule 13.2 and where unity of invention is present.

> **The method for determining unity of invention under Rule 13.2 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:**
>
> **(i) in addition to an independent claim for a given product, an independent claim for a process specifically adapted for the manufacture of the said product, and an independent claim for a use of the said product, or**
>
> **(ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process, or**
>
> **(iii) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product and an independent claim for an apparatus or means specifically designed for carrying out the said process,... *Annex B, Administrative Instructions Under the PCT.***

In the present case, Claim 1-26 (or Group I as restricted by the Examiner) and claim 27-30 (or Group II) are related as systems and methods for treating or preventing atherosclerosis, stenosis, restenosis, smooth muscle cell proliferation or other abnormal luminal cellular proliferation condition. The present systems and methods form a single general inventive concept just as the apparatus or means, product and process form a single general inventive concept in the quoted examples found in Annex B, Administrative Instructions Under the PCT. In instant systems and methods are all directed to the goal of treating or preventing atherosclerosis, stenosis, restenosis, smooth muscle cell proliferation or other abnormal luminal cellular proliferation condition.

In view of the foregoing, Applicants respectfully request the Examiner reconsider and withdraw the restriction requirement. It is also submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicant's undersigned attorney.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-3207.

Respectfully submitted,

Dated: 3 June 2008

/Daniel S. Kim/
Daniel S. Kim
Registration No. 51877
CUSTOMER NUMBER: 45,200

K&L GATES LLP
1900 Main Street, Suite 600
Irvine, California 92614-7319
Telephone: (949) 253-0900
Facsimile: (949) 253-0902